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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,398	12/23/2003	Syamal Raychaudhuri	037003-0307430	7187
909	7590	03/28/2005		EXAMINER
PILLSBURY WINTHROP, LLP				HILL, MYRON G
P.O. BOX 10500				
MCLEAN, VA 22102			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/743,398	RAYCHAUDHURI ET AL.	
	Examiner Myron G. Hill	Art Unit 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

#### **Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 23 December 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/24/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

This action is in response to papers filed 23 December 2003.

Claim 1 is under consideration.

### ***Information Disclosure Statement***

A signed and initialed copy of the IDS filed 24 May 2004 is enclosed with this action.

### ***Priority***

Applicant is requested to update the priority statement on the first line of the specification to reflect that 09/740,003 is now US 6,733,763.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5709860. This is a double patenting rejection.

Claim 1 is identical to claim 1 of US 5709860.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5695770. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim is drawn to a species of the pending claim and the species makes obvious the genus. The patented claim is drawn to the same composition comprising a "papillomavirus" antigen and a three part antigen formulation.

Thus, the species of the patent makes obvious the genus composition claim of the application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Howell *et al.*

(US 3083142, it is noted that the USPTO database (BRS) lists the patent as

ROSCMARY[*sic*] HEATH KATHLEEN; et. al., the third named inventor).

The claim is drawn to a product which is a composition comprising an antigen mixed with a microfluidized formulation comprising a stabilizing detergent, a micelle forming agent, and a biodegradable/biocompatible oil. The limitation “microfluidized” does not change the components of the composition. The limitation could be used as a “step” in a method claim (a method of making an antigenic formulation) but in a product claim the “step” does not change the components. Page 8 of the specification defines the components of the composition and provides a non-limiting list of examples.

Howell *et al.* teach compositions of stabilized oil in water emulsions (column 1, lines 41-60). The compositions comprise stabilizing detergent and micelle forming agents (components listed in Types (a) and (b) (column 2, line 45- column 3, line3), Type (a) are stabilizing agents and (b) are emulsifying agents (column 2, lines 62-65), biocompatible oil (column 3, lines 67-75), and mixed with an antigen (column 4, line 50 and following).

Thus, Howell *et al.* anticipate the claimed invention.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Glass *et al.* (US 3919411).

The claim is drawn to a product which is a composition comprising an antigen mixed with a microfluidized formulation comprising a stabilizing detergent, a micelle forming agent, and a biodegradable/biocompatible oil. The limitation "microfluidized" does not change the components of the composition. The limitation could be used as a "step" in a method claim (a method of making an antigenic formulation) but in a product claim the "step" does not change the components. Page 8 of the specification defines the components of the composition and provides a non-limiting list of examples.

Glass *et al.* teach compositions of a stabilizing detergent, a micelle forming agent, and a biodegradable/biocompatible oil (Tween 80, Carbopol and cotton seed oil as adjuvant in Example 3 used with an antigen of column 2, lines 15-35)

Thus, Glass *et al.* anticipate the claimed invention.

### ***Conclusion***

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

*MH*  
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Patent Examiner  
March 17, 2005

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3/17/05  
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